

CLAIMS

We claim:

- 1           1.       A pharmaceutical composition in blended or granulated form for the  
2       treatment of histamine-induced disorders, comprising a therapeutically effective amount  
3       of descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and a  
4       pharmaceutically acceptable inert carrier.
- 1           2.       The pharmaceutical composition of claim 1 wherein the pharmaceutical  
2       composition is substantially free of reactive excipients.
- 1           3.       The pharmaceutical composition of claim 2 wherein the pharmaceutical  
2       composition is substantially free of lactose.
- 1           4.       The pharmaceutical composition of claim 1 wherein the therapeutically  
2       effective amount of descarboethoxyloratadine is about 0.1 mg to 10 mg.
- 1           5.       The pharmaceutical composition of claim 4 wherein the therapeutically  
2       effective amount of descarboethoxyloratadine is about 0.1 mg to 5 mg.
- 1           6.       The pharmaceutical composition of claim 1 further comprising a  
2       therapeutically effective amount of an analgesic.
- 1           7.       The pharmaceutical composition of claim 6 wherein the analgesic is  
2       selected from the group consisting of acetylsalicylic acid, acetaminophen, ibuprofen,  
3       ketoprofen, naproxen or a pharmaceutically acceptable salt thereof.
- 1           8.       The pharmaceutical composition of claim 1 further comprising a  
2       therapeutically effective amount of a decongestant.
- 1           9.       The pharmaceutical composition of claim 1 wherein the composition is  
2       present in one of tablet or capsule form.

1 10. The pharmaceutical composition of claim 7 wherein the composition is  
2 present in tablet form.

1 11. A method of treating cough, cold, cold-like and flu symptoms and the  
2 discomfort, headache, pain, fever and general malaise associated therewith, comprising  
3 administering a pharmaceutical composition according to claim 1.

1 12. A method of treating diabetic retinopathy or other small vessel disorders  
2 associated with diabetes melitis, comprising administering a pharmaceutical composition  
3 according to claim 1.

1 13. A method of treating symptomatic dermographism or dermatitis,  
2 comprising administering a pharmaceutical composition according to claim 1.

1 14. A method of treating allergic rhinitis, comprising administering a  
2 pharmaceutical composition according to claim 1.

1 15. A method of treating histamine-induced disorders, comprising  
2 administering a pharmaceutical composition according to claim 1.

1 16. An anhydrous pharmaceutical composition for the treatment of histamine-  
2 induced disorders, comprising a therapeutically effective amount of  
3 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and a  
4 pharmaceutically acceptable carrier.

1 17. The anhydrous pharmaceutical composition of claim 16 wherein the  
2 therapeutically effective amount of descarboethoxyloratadine is about 0.1 mg to 10 mg.

1 18. The anhydrous pharmaceutical composition of claim 17 wherein the  
2 therapeutically effective amount of descarboethoxyloratadine is about 0.1 mg to 5 mg.

1 19. The anhydrous pharmaceutical composition of claim 16 further  
2 comprising a therapeutically effective amount of an analgesic.

1 20. The anhydrous pharmaceutical composition of claim 19 wherein the  
2 analgesic is selected from the group consisting of acetylsalicylic acid, acetaminophen,  
3 ibuprofen, ketoprofen, naproxen or a pharmaceutically acceptable salt thereof.

4 21. The anhydrous pharmaceutical composition of claim 16 further  
5 comprising a therapeutically effective amount of a decongestant.

1 22. The anhydrous pharmaceutical composition of claim 16 wherein the  
2 composition is present in one of tablet or capsule form.

1 23. The anhydrous pharmaceutical composition of claim 22 wherein the  
2 composition is present in tablet form.

1 24. A method of treating cough, cold, cold-like and flu symptoms and the  
2 discomfort, headache, pain, fever and general malaise associated therewith, comprising  
3 administering an anhydrous pharmaceutical composition according to claim 16.

1 25. A method of treating diabetic retinopathy or other small vessel disorders  
2 associated with diabetes melitis, comprising administering an anhydrous pharmaceutical  
3 composition according to claim 16.

1 26. A method of treating symptomatic dermographism or dermatitis,  
2 comprising administering an anhydrous pharmaceutical composition according to claim  
3 16.

1 27. A method of treating allergic rhinitis, comprising administering an  
2 anhydrous pharmaceutical composition according to claim 16.

1 28. A method of treating histamine-induced disorders, comprising  
2 administering an anhydrous pharmaceutical composition according to claim 16.

1           29.     A non-hygroscopic pharmaceutical composition comprising  
2     descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, lactose and one  
3     or more pharmaceutically acceptable inert excipients wherein the composition is  
4     substantially free of unbound water.

1           30.     The non-hygroscopic pharmaceutical composition of claim 29 wherein  
2     the one or more pharmaceutically acceptable inert excipients is selected from the group  
3     consisting of non-hygroscopic excipients and low-moisture excipients.

4           31.     A solid, non-hygroscopic pharmaceutical composition comprising  
5     descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and a  
6     pharmaceutically acceptable carrier.

1           32.     An uncoated pharmaceutical composition substantially free of reactive  
2     excipients comprising descarboethoxyloratadine, or a pharmaceutically acceptable salt  
3     thereof, and a pharmaceutically acceptable carrier.

1           33.     A chemically stable pharmaceutical composition in blended or granulated  
2     dosage form and substantially free of reactive excipients comprising about 1 % to about  
3     50% by weight of descarboethoxyloratadine, or a pharmaceutically acceptable salt  
4     thereof, and about 99% to about 50% by weight of a pharmaceutically acceptable inert  
5     carrier.

1           34.     A pharmaceutical composition for the treatment of histamine-induced  
2     disorders comprising large particles of descarboethoxyloratadine, or a pharmaceutically  
3     acceptable salt thereof, and a pharmaceutically acceptable carrier.

1           35.     The pharmaceutical composition of claim 34 wherein the  
2     descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, present in the  
3     composition has a particle size distribution in which greater than about 40% by weight of  
4     the descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, comprises  
5     particles having a size of 250  $\mu\text{m}$  or larger.

1           36.     A solid pharmaceutical composition for the treatment of histamine-  
2 induced disorders comprising a therapeutically effective amount of coated  
3 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, which comprises  
4 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, coated with an  
5 inert coating agent, and a pharmaceutically acceptable carrier.

1           37.     The solid pharmaceutical composition of claim 36 wherein the coated  
2 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, further comprises  
3 a granulated formulation of descarboethoxyloratadine, or a pharmaceutically acceptable  
4 salt thereof, and a pharmaceutically acceptable inert excipient, wherein the granulated  
5 formulation is coated with an inert coating agent.

6           38.     The solid pharmaceutical composition of claim 36 or 37 wherein the inert  
7 coating agent comprises an inert film-forming agent in a solvent.

1           39.     The solid pharmaceutical composition of claim 38 wherein the inert film-  
2 forming agent is selected from the group consisting of methylcellulose, hydroxymethyl  
3 cellulose, carboxymethylcellulose, hydroxypropylmethylcellulose, hydroxypropyl  
4 cellulose, hydroxyethylcellulose, methylhydroxyethylcellulose and sodium  
5 carboxymethylcellulose.

1           40.     An instant release solid pharmaceutical dosage form for treating  
2 histamine-induced disorders, comprising an open matrix network carrying a  
3 therapeutically effective amount of descarboethoxyloratadine, or a pharmaceutically  
4 acceptable salt thereof, wherein the open matrix network comprises a pharmaceutically  
5 acceptable water-soluble or water-dispersible carrier that does not interact with the  
6 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof.

ADD #2